

REMARKS

These remarks are in response to the Office Action mailed January 30, 2003, and the Advisory Action mailed April 29, 2003.

Claims 3, 10 and 11 have been cancelled. Claims 2, 5, 6 and 8 are allowable. Claims 1, 9, 13 and 14 have been amended.

Support for the amended claims can be found throughout the specification. No new matter has been added. Claims 1, 2, 4-6, 8, 9 and 12-17 are pending and at issue. Exhibits A, B and C are attached to the current amendment to clarify the term "formed elements." Applicants respectfully request reconsideration of the present application.

Claim Objections

Claim 8 is objected to because the recitation of "Si" appears to be "Sl." Applicants have amended the claim to clarify the recitation of "Si."

Claim 17 is objected to as lacking a period. Applicant notes that the claims have been amended so as to include periods.

In view of the amendments to the claims, Applicant submits that the present objection is moot and respectfully requests its withdrawal.

I. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the recitation of "formed elements." Specifically, the Office Action alleges that the recited term is not art recognized. Applicants respectfully traverse this rejection.

Applicants note that the present invention provides an improved means for stabilizing the pH of a patients blood during

dialysis (see Example 8, Page 10). In the field of hematology, blood is known to be composed of a solid, cellular portion, termed "formed elements," and a fluid portion, termed "plasma." The solid elements are suspended and carried in the plasma, which contains many different types of proteins and water-soluble molecules. The term "formed elements" means the components of blood that do not dissolve in the plasma (i.e., cells and platelets). In support of this, Applicants provide Exhibits A, B and C. The Exhibits clearly indicate that the medical community recognizes blood as comprising four components: 1) red blood cells; 2) white blood cells; 3) platelets; and 4) plasma (see Exhibit C, paragraph 1 "What is blood"). As indicated in Exhibits A and B, red blood cells, white blood cells and platelets are routinely referred to as "formed elements" by the skilled artisan.

Applicants submit that the term "formed elements" is an art recognized term which does not render the claim indefinite. If those skilled in the art can tell whether a particular embodiment is or is not within the scope of a claim, the claim is sufficiently definite. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The present specification clearly discloses a novel method for adjusting the pH of blood and one skilled in the medical arts would certainly recognize that plasma and formed elements are components of blood.

In view of the above discussion, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH*Written Description*

Claims 4 and 9-17 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Specifically, the Office Action that the recitation of "formed elements" and "membrane is associated with an acidic compound capable of modifying the pH of the fluid" in claim 4 is new matter because they were not present in the specification as filed. As noted above, Applicants contend that "formed elements" are easily recognized by the skilled artisan as components of blood. The recitation of "blood" (page 10, line 5) in the specification conveys with reasonable clarity that the inventors were in possession of a method for modifying the pH of a "fluid comprising plasma and suspended formed elements" at the time the application was filed.

With regard to the recitation of a lipid membrane "associated with an acidic compound capable of modifying the pH of the fluid," Applicants point to page 10, lines 7-17, which state:

Current methods for dialysis employ systems wherein ammonia is transported across a **dialysis membrane** and is trapped by an **acidic compound such as citric acid**. Disadvantages of currently used dialysis membranes include short shelf life and instability during usage. The sol-gel **encapsulated phospholipid vesicles of the present invention may be used in dialysis membranes**, thus affording a more stable and efficient dialysis system than the currently used citric acid-based

membrane. Ammonia exchange was quantitated by passing a solution of ammonium phosphate through the sol-gel encapsulated vesicle membrane and determining the output pH value (emphasis added).

The passage clearly supports Applicants contention that they were in possession of a method for modifying the pH of a fluid using a lipid membrane "associated with an acidic compound" at the time the application was filed.

With regard to the recitation of "stabilizing the lipid membrane," Applicants point to page 4, lines 28-34, of the specification, which state:

The silyl lipid functions not only as a component lipid molecule to form a bilayer or multilayer structure in the LB membrane or vesicle, but also as a cross-linking seed such that condensation of the silanol head with the silyl lipid results in the formation of a fine mesh at the surface of the lipid membrane or vesicle, thus **enhancing the stability** of the membrane or vesicle (emphasis added).

This passage clearly supports Applicants contention that they were in possession of a method for enhancing the stability of a lipid membrane at the time the application was filed.

With regard to the recitation of "formed elements," the Examiner states at page 3, lines 2-4, that "it is not clear that this term is necessarily limited to blood, but in any case applicant's original disclosure merely refers to plasma and it is not clear that whole plasma was intended." Applicants point to page 10, lines 4-6, of the specification, which state:

Patients with renal failure develop acid/base imbalance in the **blood stream** and, therefore, require regular dialysis to maintain the appropriate blood pH (emphasis added).

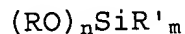
The specification clearly intended to convey to the skilled artisan that the sol-gel encapsulated phospholipid vesicles of the present invention can be used to filter blood during dialysis.

Accordingly, Applicants respectfully request that these rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

### III. REJECTIONS UNDER 35 U.S.C. §102

Claims 1, 9, 10 and 13-16 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lanquetin. In addition, claims 1, 9 and 12-16 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nakamura. Applicants respectfully traverse these rejections as they may apply to the amended claims.

Independent claim 1 has been amended to recite a silyl lipid molecule having the formula:



Furthermore, independent claim 9 has been amended to incorporate the limitations of canceled claims 10 and 11 and to recite a lipid membrane comprising "...phospholipids and protein..."

In view of the amendments to the claims, Applicants submit that neither Lanquetin nor Nakamura teach each element of any claim under consideration. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §102(b) be withdrawn.

Conclusion

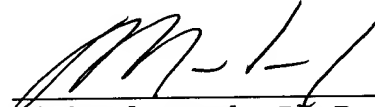
In summary, for the reasons set forth herein, Applicants maintain that claims 1, 2, 4-6, 8, 9 and 12-17 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action and the Advisory Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (858) 678-5070. Please charge any fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

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